6. 510(k) Summary

MAY 2 9 2013

CASMED®

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: CAS Medical Systems, Inc.

Address: 44 East Industrial Rd. Branford CT. 06405 USA

Contact: Ron Jeffrey – Director, Regulatory Affairs
Phone - (203) 488-6056
Fax – (203) 488-9438
Email – rjeffrey@casmed.com

Prepared: February 15, 2013

Trade Name: 740 SELECT™

Common Name: Monitor, Physiological, Patient

Classification Name: Cardiovascular Monitoring Device 870.2300 (MWI)

EQUIVALENCE (Predicate Device)

The 740 SELECT is equivalent to the following device:

- CAS 740 Series Monitor (K033048)

DESCRIPTION

The 740 SELECT Series Monitor is a portable and rugged non-invasive multi-parameter device used for spot checking, continuous monitoring, and recording of blood pressure, pulse rate, functional oxygen saturation (%Sp02), and predictive body temperature in a variety of clinical environments. The Monitor includes features that are optional or configurable.

The 740 SELECT Series Monitor is compact and lightweight in design, allowing it to be easily carried and or configured for use with a mobile stand, wall mount or on a table top.

A Lithium Ion (Li-Ion) rechargeable battery is provided for automatic switching to back-up power if an untended loss of AC power should occur as well as allow the monitor to be used for clinical applications when portable monitoring is required.

The 740 SELECT Series Monitor is equipped with a color touchscreen which is the primary interface for the user to control and configure the Monitor (for patient type, alarms, settings and various clinical workflows). A dedicated message area provides patient alarm and technical messages. Date and time as well as the Monitor ID are displayed. A battery gauge provides approximate battery capacity when the monitor is operating on battery power.

The Monitor supports both point-of-care and variable acuity monitoring. Spot vital signs measurements from multiple patients can be saved individually. The monitor can be used for continuous patient monitoring with full alarm support when increased vigilance in necessary based on patient acuity.

The Stand-By Mode provides enhanced bedside patient workflow and alarm management permitting sensor attachment, automatic alarm suspension and switch to active monitoring.

The color coded Trends Display allows the user to recall all trended physiologic patient measurement records. Trends can be recalled for saved snapshots as well as timed intervals.

The Monitor provides a screen keyboard for entry of patient data (e.g., age, weight, height, gender, date of birth, patient name, and patient identification number).

A serial data output is provided for connectivity to hospital EMR systems and external serial devices. An internal isolated relay switch is provided for nurse call systems. The monitor supports an optional externally connected thermal strip chart recorder which is directly powered from the serial port.

The MAXNIBP™ non-invasive blood pressure (NIBP) parameter automatically inflates an occluding cuff and, using the oscillometric measurement technique, determines systolic, diastolic and mean arterial pressure as well as pulse rate. Measurement results along with user prompts and error messages are displayed in the dedicated message area on the display screen. The frequency of NIBP determination can be selected by the user in varied times between one and ninety minutes. The AUTO, MANUAL and STAT modes are available to cover a variety of clinical uses.

The pulse oximeter parameter (%SpO2) determines arterial hemoglobin oxygen saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate. The oximeter requires no routine calibration or maintenance. Monitors with the SpO2 option are provided with the ability to display the plethysmograph waveform (in spot and or continuous monitoring mode). A signal strength bar provides relative quality of the SpO2 value based on the measurement site where the sensor is placed. An audio pulse tone "beep" can be generated each time the SpO2 module detects a pulse.

A pulse rate is displayed and appropriately color coded to indicate the source parameter (SpO2 or NIBP) of the displayed.

The temperature parameter has the capability of taking temperature in either normal (predictive) or monitor mode. In the normal mode, the thermometer's microprocessor "predicts" body temperature in about four (4) seconds for oral temperatures, about ten (10) seconds for axillary temperatures and about fifteen (15) seconds for rectal temperatures. The default setting used by the monitor for Temperature determinations is the Predictive (normal) mode. Upper and lower Temperature alarm limits can be enabled. The last temperature measurement time is displayed for reference.

Alarm conditions are displayed as text messages in a dedicated area on the bottom of the display screen. A recurring series of alert tones are provided to indicate: an alarm limit has been violated, alert user to a specific monitor operation (e.g., battery low), or a condition exists that affects patient safety. Visual cues (flashing background) are displayed within a parameter cell to indicate an alert is currently active for that parameter. A solid background indicates an alert is currently active for that parameter but the audio tone has been silenced.

The 740 SELECT Intended Use

The 740 SELECT is indicated for use as a bedside, portable device for use by health care professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult, pediatric and neonatal patients. The Monitor features world class technology to facilitate the monitoring of non-invasive blood pressure, pulse rate, functional arterial oxygen saturation (Sp02) and body temperature in a variety of clinical environments.

740 SELECT Monitor Technologies Compared to Predicate Devices

The 740 SELECT compares substantially to the cited predicate device in that it uses fundamentally the same technologies for the common parameters. The non-invasive blood pressure component is the CASMED MAXNIBP an oscillometric instrument having neither a stethoscope nor a microphone and does not need the quiet environment necessary to detect the auscultatory sounds. Oscillometric instruments work on the principle that when the artery opens during a portion of the pressure cycle, an oscillation is superimposed on the pressure inside the cuff due to a tiny enlargement of the circumference of the limb caused by the surge of blood under the cuff. The amplitude of the oscillometric signals change over the course of the deflation of the cuff. Oscillometric devices look for oscillation amplitude of certain percentages of the maximum amplitude at mean arterial pressure (MAP), defining one percentage as the systolic point and another as the diastolic point. Alternatively, a combination of the amplitude, the slope of the increase or decrease, and some other complex factors are used to find these points.

The 740 SELECT pulse oximeter can include either of two industry leading components specific to the customer's requirement. Masimo Rainbow SET® or Nellcor's NELL 1 technology. The pulse oximeter parameter (%SpO2) determines arterial oxyhemoglobin saturation by measuring the absorption of red and infrared light passing through the tissue. Changes in absorption caused by pulsations of blood in the vascular bed are used to determine arterial saturation and pulse rate.

The temperature parameter has the capability of taking temperature in either normal (predictive) or monitor mode. In the normal mode, the thermometer's microprocessor "predicts" body temperature in about four (4) seconds for Oral temperatures, about ten (10) seconds for Axillary temperatures and in about fifteen (15) seconds for Rectal temperatures.

Non-Clinical Performance Testing to Demonstrate Substantial Equivalence

The 740 SELECT has successfully undergone extensive performance, safety, electromagnetic, and environmental testing to ensure it has been found to be substantially equivalent to the primary and secondary predicate devices. In addition to the above laboratory tests, CAS has conducted a full program of individual hardware, software and systems verification and validation studies of the monitor and accessories.

Clinical Testing to Show Substantial Equivalence

The 740 SELECT has successfully undergone extensive clinical validation for the indicated use. The premarket notification cites clinical validation reports for the NIBP, pulse oximeter and the temperature function.

Conclusions Drawn from Clinical and Non-Clinical Testing

Clinical evaluation, safety testing, software and systems validation demonstrate the 740 SELECT is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

May 29, 2013

Cas Medical Systems, Inc.
Ron Jeffrey
44 East Industrial Rd.
Branford, CT 06405 US

Re: K130411
Trade/Device Name: 740 select
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiovascular Monitoring Device
Regulatory Class: Class II
Product Code: MWI
Dated: February 15, 2013
Received: February 28, 2013

Dear Ron Jeffrey:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, Misbranding by reference to premarket notification (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htmfor the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number: K130411

Device Name: 740 SELECT

Indications for Use:

The 740 SELECT is indicated for use as a bedside, portable device for use by health care professionals, clinicians and medically qualified personnel for spot checking, continuous monitoring and recording of adult, pediatric and neonatal patients. The Monitor features world class technology to facilitate the monitoring of non-invasive blood pressure, pulse rate, functional arterial oxygen saturation (Sp02) and body temperature in a variety of clinical environments.

Prescription Use ✔ AND/OR Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
2013.05.29 09:25:50
04'00'